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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

JANEEN BRIDA, Individually and as Trustee
Ad Litem on behalf of all parties entitled by law to

Damages in the death of JEROME HEFFNER, SR., Deceased.

Plaintiff,

07 CIV 8060 (JSR)(DFE) ECF CASE

-against-

PFIZER INC., PARKE DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY and WARNER-LAMBERT COMPANY LLC,

De	efendants.	
	X	

ANSWER

Defendants Pfizer Inc. ("Pfizer") and Warner-Lambert Company LLC, formerly known as Warner-Lambert Company ("Warner-Lambert"), on its own behalf and on behalf of its unincorporated division, Parke-Davis (collectively referred to hereinafter as "Defendants"), by their undersigned counsel, answer Plaintiff's Complaint in the above-captioned action (the "Complaint") as follows:

AS TO STATEMENT OF THE CASE

1. Deny the allegations in paragraph 1, except admit that the United States Food and Drug Administration ("FDA") has approved Neurontin® ("Neurontin"), the brand name for

gabapentin, for labeling as safe and effective only as adjunctive therapy in the treatment of partial seizures in patients with epilepsy and in the management of postherpetic neuralgia.

AS TO PARTIES AND JURISDICTION

- 2. Paragraph 2 and its subparts assert legal conclusions to which no response is required, and Defendants therefore deny the allegations in paragraph 2 and its subparts, except admit: (1) that Pfizer is a Delaware corporation and has its headquarters in the State of New York; (2) that Warner-Lambert Company was a wholly-owned subsidiary of Pfizer from June 2000 through December 31, 2002, when it was converted into a Delaware limited liability company known as Warner-Lambert Company LLC with Pfizer as its sole member; (3) that Parke-Davis is an unincorporated division of Warner-Lambert Company LLC; and (4) upon information and belief, that the parties are diverse and the amount in controversy exceeds the sum of \$75,000, exclusive of interest and costs.
- 3. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3, and therefore deny same, except admit Plaintiff seeks the relief stated in paragraph 3, but deny that Plaintiff is entitled to such relief.
- 4. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4, and therefore deny same.
- 5. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5, and therefore deny same.
 - 6. Admit the allegations in paragraph 6.
 - 7. Admit the allegations in paragraph 7.
 - 8. Admit the allegations in paragraph 8.
 - 9. Deny the allegations in paragraph 9.

- 10. Deny the allegations in paragraph 10.
- 11. Deny the allegations in paragraph 11.
- 12. Deny the allegations in paragraph 12, except admit that Warner-Lambert Company was a Delaware corporation until December 31, 2002, when it was converted into a Delaware limited liability company, known as Warner-Lambert Company LLC.
- 13. Deny the allegations in paragraph 13, except admit that Warner-Lambert Company was authorized to do business in the State of New York until December 31, 2002.
- 14. Deny the allegations in paragraph 14, except admit that Warner-Lambert Company was a business entity actually doing business in the State of New York until December 31, 2002.
- 15. Deny the allegations in paragraph 15, except admit that Parke-Davis was a division of Warner-Lambert Company from approximately 1978 until approximately June 2000.
 - 16. Deny the allegations in paragraph 16.
- 17. Deny the allegations in paragraph 17, except admit that from December 31, 2002 to the present Warner-Lambert Company LLC has been a Delaware limited liability company.
- 18. Deny the allegations in paragraph 18, except admit that Warner-Lambert Company LLC is a Delaware limited liability company authorized to do business in the State of New York since December 31, 2002.
- 19. Deny the allegations in paragraph 19, except admit that Warner-Lambert Company LLC has been a business entity actually doing business in the State of New York since December 31, 2002.
- 20. Deny the allegations in paragraph 20, except admit that Pfizer is and has been the sole member of Warner-Lambert Company LLC since December 31, 2002.

- 21. Deny the allegations in paragraph 21.
- 22. Deny the allegations in paragraph 22.
- 23. Deny the allegations in paragraph 23.
- 24. Deny the allegations in paragraph 24, except admit that Warner-Lambert Company was a wholly-owned subsidiary of Pfizer from June 2000 through December 31, 2002.
- 25. Paragraph 25 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 25.
 - 26. Deny the allegations in paragraph 26.
- 27. Deny the allegations in paragraph 27, except admit that Warner-Lambert Company LLC has been a wholly-owned subsidiary of Pfizer since December 31, 2002.
- 28. Paragraph 28 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 28.
- 29. Paragraph 29 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 29.
- 30. Paragraph 30 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 30.
- 31. Paragraph 31 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 31.
- 32. Paragraph 32 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 32.
- 33. Paragraph 33 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 33.

- 34. Paragraph 34 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 34.
- 35. Paragraph 35 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 35.
- 36. Paragraph 36 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 36.
- 37. Paragraph 37 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 37.
- 38. Paragraph 38 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 38.
- 39. Paragraph 39 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 39.
- 40. Paragraph 40 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 40.
- 41. Paragraph 41 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 41.
- 42. Paragraph 42 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 42.
- 43. Paragraph 43 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 43.
- 44. Paragraph 44 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 44.

- 45. Paragraph 45 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 45.
- 46. Paragraph 46 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 46.
- 47. Paragraph 47 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 47.
- 48. Paragraph 48 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 48.
- 49. Paragraph 49 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 49.
- 50. Paragraph 50 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 50.
- 51. Paragraph 51 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 51.
- 52. Paragraph 52 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 52.
- 53. Paragraph 53 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 53.
- 54. Paragraph 54 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 54.
- 55. Paragraph 55 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 55.

- 56. Paragraph 56 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 56.
- 57. Paragraph 57 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 57.
- 58. Paragraph 58 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 58.
- 59. Paragraph 59 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 59.
- 60. Paragraph 60 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 60.
- 61. Paragraph 61 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 61.
- 62. Paragraph 62 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 62.
- 63. Paragraph 63 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 63.
- 64. Paragraph 64 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 64.
- 65. Paragraph 65 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 65.
- 66. Paragraph 66 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 66.

- 67. Paragraph 67 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 67.
- 68. Paragraph 68 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 68.
- 69. Deny the allegations in paragraph 69, except admit that Pfizer's headquarters are in New York.
- 70. Paragraph 70 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 70.
- 71. Paragraph 71 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 71.
- 72. Paragraph 72 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 72.
- 73. Deny the allegations in paragraph 73, except admit that since June 2000, Pfizer, directly and/or indirectly through its subsidiaries, has marketed and sold Neurontin.
- 74. Deny the allegations in paragraph 74, except admit that Pfizer, directly and/or indirectly through its subsidiaries, has marketed and sold Neurontin since June 2000.
- 75. Deny the allegations in paragraph 75, except admit that Pfizer is engaged, directly and/or indirectly through its subsidiaries, in the business of designing, manufacturing, advertising, marketing and selling pharmaceutical drugs, and transacts business within the State of New York and contracts to provide goods in the State of New York.
 - 76. Deny the allegations in paragraph 76.
 - 77. Deny the allegations in paragraph 77.
 - 78. Admit the allegations in paragraph 78.

- 79. Deny the allegations in paragraph 79.
- 80. Deny the allegations in paragraph 80.
- 81. Deny the allegations in paragraph 81, except admit that Parke-Davis marketed Neurontin on a date prior to September 16, 2005.
- 82. Deny the allegations in paragraph 82, except admit that Parke-Davis was a division of Warner-Lambert Company from approximately 1978 until approximately June 2000, and that until approximately June 2000, Parke-Davis directly and/or indirectly engaged in the business of marketing pharmaceutical drugs, including Neurontin, and transacted business within the State of New York and contracted to provide goods in the State of New York.
 - 83. Deny the allegations in paragraph 83.
 - 84. Deny the allegations in paragraph 84.
- 85. Deny the allegations in paragraph 85, except admit that Parke-Davis was a division of Warner-Lambert Company from approximately 1978 until June 2000 and that until June 2000, Parke-Davis directly or indirectly did and solicited business and engaged in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.
 - 86. Deny the allegations in paragraph 86.
 - 87. Deny the allegations in paragraph 87.
- 88. The allegations in paragraph 88 are unintelligible as written and Defendants therefore deny same, except admit that Warner-Lambert Company marketed and sold Neurontin until June 2000.
- 89. Deny the allegations in paragraph 89, except admit that until December 31, 2002, Warner-Lambert Company was, directly and/or indirectly, engaged in the business of designing,

manufacturing, advertising, marketing, and selling pharmaceutical drugs and transacted business within the State of New York and contracted to provide goods in the State of New York.

- 90. Deny the allegations in paragraph 90.
- 91. Deny the allegations in paragraph 91.
- 92. Deny the allegations in paragraph 92, except admit that until June 2000, Warner-Lambert Company, directly and/or indirectly, did and solicited business and engaged in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.
 - 93. Deny the allegations in paragraph 93.
 - 94. Deny the allegations in paragraph 94.
 - 95. Deny the allegations in paragraph 95.
 - 96. Deny the allegations in paragraph 96.
 - 97. Deny the allegations in paragraph 97.
 - 98. Deny the allegations in paragraph 98.
- 99. Deny the allegations in paragraph 99, except admit that since December 31, 2002, Warner-Lambert Company LLC has done and solicited business and engaged in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.
- 100. Deny the allegations in paragraph 100, except admit that since December 31, 2002, Warner-Lambert Company LLC has done and solicited business and engaged in a persistent course of conduct in the State of New York, deriving substantial revenue from interstate commerce.

AS TO BACKGROUND

- 101. Paragraph 101 does not allege facts to which a response is required, and Defendants therefore deny the allegations in paragraph 101.
- 102. Paragraph 102 does not allege facts to which a response is required, but to the extent that a response might be deemed required, Defendants admit the allegations in paragraph 102.
- 103. Paragraph 103 does not allege facts to which a response is required, and Defendants therefore deny the allegations in paragraph 103.
- 104. Paragraph 104 does not allege facts to which a response is required, and Defendants therefore deny the allegations in paragraph 104.
- 105. Paragraph 105 does not allege facts to which a response is required, and Defendants therefore deny the allegations in paragraph 105.
- 106. Paragraph 106 does not allege facts to which a response is required, and Defendants therefore deny the allegations in paragraph 106.
- 107. Deny the allegations in paragraph 107, except admit that, in 1993, the FDA approved Neurontin for labeling as safe and effective for adjunctive therapy in the treatment of partial seizures in patients with epilepsy at dosages of 900 to 1800 milligrams per day.
- 108. Deny the allegations in paragraph 108, except admit that the FDA has approved Neurontin for labeling as safe and effective only as adjunctive therapy in the treatment of partial seizures in patients with epilepsy and in the management of postherpetic neuralgia.
 - 109. Deny the allegations in paragraph 109.
 - 110. Deny the allegations in paragraph 110.
 - 111. Deny the allegations in paragraph 111.

- 112. Deny the allegations in paragraph 112.
- 113. Deny the allegations in paragraph 113.
- 114. Deny the allegations in paragraph 114.
- 115. Deny the allegations in paragraph 115, except admit that Neurontin was approved as adjunctive therapy for the treatment of epilepsy.
 - 116. Deny the allegations in paragraph 116.
 - 117. Deny the allegations in paragraph 117.
- 118. Deny the allegations in paragraph 118, except admit that on May 13, 2004, an Information was filed against Warner-Lambert Company LLC in the United States District Court for the District of Massachusetts.
 - 119. Deny the allegations in paragraph 119.
 - 120. Deny the allegations in paragraph 120.
- 121. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 121, and therefore deny same.
- 122. Deny the allegations in paragraph 122, except deny knowledge or information sufficient to form a belief as to the truth of the allegations that Decedent's physician prescribed Neurontin to treat Decedent's depression, and therefore deny same.
- 123. Deny the allegations in paragraph 123, except deny knowledge or information sufficient to form a belief as to the truth of the allegations that Decedent's physician prescribed Neurontin to treat Decedent's depression, and therefore deny same.
 - 124. Deny the allegations in paragraph 124.
 - 125. Deny the allegations in paragraph 125.
 - 126. Deny the allegations in paragraph 126.

127. Deny the allegations in paragraph 127.

AS TO FIRST CAUSE OF ACTION

- 128. Repeat each and every response to the allegations in paragraphs 1 through 127.
- 129. Deny the allegations in paragraph 129.
- 130. Deny the allegations in paragraph 130.
- 131. Deny the allegations in paragraph 131.
- 132. Paragraph 132 asserts legal conclusions to which no response is required, and Defendants therefore deny the allegations in paragraph 132.
 - 133. Deny the allegations in paragraph 133.
 - 134. Deny the allegations in paragraph 134.
 - 135. Deny the allegations in paragraph 135.
 - 136. Deny the allegations in paragraph 136.
 - 137. Deny the allegations in paragraph 137.
 - 138. Deny the allegations in paragraph 138.
 - 139. Deny the allegations in paragraph 139.
- 140. Deny the allegations in paragraph 140, except admit that Plaintiff seeks the relief stated in paragraph 140, but deny that Plaintiff is entitled to such relief.

AS TO SECOND CAUSE OF ACTION

- 141. Repeat each and every response to the allegations in paragraphs 1 through 140.
- 142. Deny the allegations in paragraph 142.
- 143. Deny the allegations in paragraph 143.
- 144. Deny the allegations in paragraph 144.
- 145. Deny the allegations in paragraph 145.

- 146. Deny the allegations in paragraph 146.
- 147. Deny the allegations in paragraph 147.
- 148. Deny the allegations in paragraph 148, except admit that Plaintiff seeks the relief stated in paragraph 148, but deny that Plaintiff is entitled to such relief.

AS TO THIRD CAUSE OF ACTION

- 149. Repeat each and every response to the allegations in paragraphs 1 through 148.
- 150. Deny the allegations in paragraph 150.
- 151. Deny the allegations in paragraph 151.
- 152. Deny the allegations in paragraph 152.
- 153. Deny the allegations in paragraph 153, except admit that Plaintiff seeks the relief stated in paragraph 153, but deny that Plaintiff is entitled to such relief.

AS TO FOURTH CAUSE OF ACTION

- 154. Repeat each and every response to the allegations in paragraphs 1 through 153.
- 155. Deny the allegations in paragraph 155.
- 156. Deny the allegations in paragraph 156.
- 157. Deny the allegations in paragraph 156, except refer to the Information for its contents.
- 158. Deny the allegations in paragraph 158, except refer to the Information for its contents.
- 159. Deny the allegations in paragraph 159, except refer to the Information for its contents.
- 160. Deny the allegations in paragraph 160, except refer to the Information for its contents.

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- 161. Deny the allegations in paragraph 161, except refer to the Information for its contents.
- 162. Deny the allegations in paragraph 162, except refer to the Information for its contents.
- 163. Deny the allegations in paragraph 163, except refer to the Information for its contents.
- Deny the allegations in paragraph 164, except refer to the Information for its 164. contents.
- 165. Deny the allegations in paragraph 165, except refer to the Information for its contents.
- 166. Deny the allegations in paragraph 166, except refer to the Information for its contents.
- 167. Deny the allegations in paragraph 167, except refer to the Information for its contents.
- 168. Deny the allegations in paragraph 168, except refer to the Information for its contents.
- 169. Deny the allegations in paragraph 169, except refer to the Information for its contents.
- 170. Deny the allegations in paragraph 170, except refer to the Information for its contents.
- Deny the allegations in paragraph 171, except refer to the Information for its 171. contents.

- 172. Deny the allegations in paragraph 172 and all of its subparts, except refer to the Information for its contents.
- 173. Deny the allegations in paragraph 173, except refer to the Information for its contents.
- 174. Deny the allegations in paragraph 174, except refer to the Information for its contents.
- 175. Deny the allegations in paragraph 175, except refer to the Information for its contents.
- 176. Deny the allegations in paragraph 176, except refer to the Information for its contents.
- 177. Deny the allegations in paragraph 177, except refer to the Information for its contents.
- 178. Deny the allegations in paragraph 178, except refer to the Information for its contents.
- 179. Deny the allegations in paragraph 179, except refer to the Information for its contents.
- 180. Deny the allegations in paragraph 180, except refer to the Information for its contents.
- 181. Deny the allegations in paragraph 181, except refer to the Information for its contents.
- 182. Deny the allegations in paragraph 182, except refer to the Information for its contents.
 - 183. Deny the allegations in paragraph 183.

- 184. Deny the allegations in paragraph 184.
- 185. Deny the allegations in paragraph 185.
- 186. Deny the allegations in paragraph 186.
- 187. Deny the allegations in paragraph 187, and all of its subparts.
- 188. Deny the allegations in paragraph 188.
- 189. Deny the allegations in paragraph 189.
- 190. Deny the allegations in paragraph 190.
- 191. Deny the allegations in paragraph 191.
- 192. Deny the allegations in paragraph 192.
- 193. Deny the allegations in paragraph 193.
- 194. Deny the allegations in paragraph 194, except refer to the supplemental NDA and the letter dated August 26, 1997 referenced in paragraph 194 for their contents.
 - 195. Deny the allegations in paragraph 195.
 - 196. Deny the allegations in paragraph 196.
- 197. Deny the allegations in paragraph 197, except refer to the letter dated June 29, 2001 for its contents.
- 198. Deny the allegations in paragraph 198, except refer to the letter dated July 1, 2002 for its contents.
 - 199. Deny the allegations in paragraph 199.
 - 200. Deny the allegations in paragraph 200.
 - 201. Deny the allegations in paragraph 201.
 - 202. Deny the allegations in paragraph 202.
 - 203. Deny the allegations in paragraph 203.

- 204. Deny the allegations in paragraph 204.
- 205. Deny the allegations in paragraph 205, except refer to the article referenced in paragraph 205 for its contents.
 - 206. Deny the allegations in paragraph 206.
 - 207. Deny the allegations in paragraph 207.
 - 208. Deny the allegations in paragraph 208.
- 209. Deny the allegations in paragraph 209, except admit that sales of Neurontin have increased since 1999 and deny knowledge or information sufficient to form a belief as to the percentage of Neurontin prescribed for off-label uses.
 - 210. Deny the allegations in paragraph 210.
 - 211. Deny the allegations in paragraph 211.
 - 212. Deny the allegations in paragraph 212.
 - 213. Deny the allegations in paragraph 213.
 - 214. Deny the allegations in paragraph 214.
- 215. Deny the allegations in paragraph 215, except admit that sales of Neurontin have increased since 1998, and deny knowledge or information sufficient to form a belief as to the percentage of Neurontin prescribed for off-label uses.
 - 216. Deny the allegations in paragraph 216.
 - 217. Deny the allegations in paragraph 217.
 - 218. Deny the allegations in paragraph 218.
 - 219. Deny the allegations in paragraph 219.
 - 220. Deny the allegations in paragraph 220.
 - 221. Deny the allegations in paragraph 221.

- 222. Deny the allegations in paragraph 222.
- 223. Deny the allegations in paragraph 223, except admit that Plaintiff seeks the relief stated in paragraph 223, but deny that Plaintiff is entitled to such relief.

AS TO FIFTH CAUSE OF ACTION

- 224. Repeat each and every response to the allegations in paragraphs 1 through 224.
- 225. Deny the allegations in paragraph 225.
- 226. Deny the allegations in paragraph 226.
- 227. Deny the allegations in paragraph 227, except admit that Plaintiff seeks the relief stated in paragraph 227, but deny that Plaintiff is entitled to such relief.

AS TO SIXTH CAUSE OF ACTION

- 228. Repeat each and every response to the allegations in paragraphs 1 through 227.
- 229. Deny the allegations in paragraph 229.
- 230. Deny the allegations in paragraph 230.
- 231. Deny the allegations in paragraph 231, except admit that Plaintiff seeks the relief set forth in paragraph 231 and the WHEREFORE paragraph following paragraph 231, and all of its subparts, but deny that Plaintiff is entitled to such relief.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in the Complaint that have not previously been specifically admitted, denied, or explained.

AFFIRMATIVE DEFENSES

Without assuming the burden of proof of such defenses that they would not otherwise have, Defendants affirmatively assert the following defenses:

FIRST AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

Pursuant to the Supremacy Clause of the United States Constitution, the claims set forth in the Complaint are preempted by federal statutes and regulations having the force of law.

THIRD AFFIRMATIVE DEFENSE

Plaintiff's Complaint is defective for failure to join indispensable parties.

FOURTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred because Decedent's alleged injuries and damages, if any, were actually or proximately caused by the intervening or superseding conduct of persons or entities over which or whom Defendants had no control.

FIFTH AFFIRMATIVE DEFENSE

Decedent's injuries and damages, if any, were due to idiosyncratic reactions to Neurontin for which Defendants cannot be held responsible.

<u>SIXTH AFFIRMATIVE DEFENSE</u>

The claims set forth in the Complaint are barred because the alleged injuries and damages, if any, were caused by medical conditions or processes (whether pre-existing or contemporaneous) unrelated to Neurontin.

SEVENTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred by the learned intermediary doctrine.

EIGHTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred by the limitations on the doctrine of strict product liability for a purported design defect and breach of warranty as set forth in the Restatement Second of Torts, Section 402A, comment K.

NINTH AFFIRMATIVE DEFENSE

To the extent Plaintiff claims a product defect, such claims are or may be barred by the doctrine described in Section 4 of the Restatement Third of Torts: Products Liability, because Defendants complied with applicable product safety statutes and administrative regulations. Neurontin, an FDA-approved prescription drug, was prepared and labeled in accordance with applicable statutes and regulations.

TENTH AFFIRMATIVE DEFENSE

To the extent Plaintiff claims product liability, Plaintiff's claims are barred by the doctrines described in Sections 6(c) and (d) of the Restatement Third of Torts: Products Liability. Reasonable physicians knowing of the reasonably foreseeable risks and therapeutic benefits associated with Neurontin would have prescribed and did prescribe Neurontin for classes of patients. In addition, Defendants provided prescribing physicians with reasonable instructions or warnings regarding foreseeable risks of harm.

ELEVENTH AFFIRMATIVE DEFENSE

To the extent Plaintiff claims a product defect, such claims are barred because, at the time the product left the control of Defendants, a practical and technically feasible alternative design or formulation was not available that would have prevented the alleged damages without substantially impairing the usefulness or intended purpose of the product.

TWELFTH AFFIRMATIVE DEFENSE

Any recovery by Plaintiff must be reduced or offset by amounts Plaintiff has received or will receive from others for the same injuries claimed in this lawsuit.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by the doctrines of release, accord, and satisfaction.

FOURTEENTH AFFIRMATIVE DEFENSE

The product may have been substantially modified and/or altered; therefore, Plaintiff's Complaint is barred.

FIFTEENTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred because the methods, standards and techniques used in formulating Neurontin and in issuing warnings and instructions about its use conformed to the generally recognized, reasonably available and reliable state of knowledge in the field at the time Neurontin was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred because Decedent's alleged injuries and damages, if any, were caused by Decedent's misuse of Neurontin.

SEVENTEENTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred because the foreseeable therapeutic benefits of Neurontin outweighed any foreseeable risks of harm.

EIGHTEENTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred by the doctrine of informed consent and assumption of risk.

NINETEENTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred because Defendants breached no warranty, express or implied, to Decedent.

TWENTIETH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred by the applicable statutes of limitation and/or repose.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred under the doctrines of estoppel, waiver, ratification, laches and unclean hands and other related doctrines and principles, or any one of them, and by Plaintiff's inequitable conduct, lack of diligence, delay and inattention in pursuing such claims.

TWENTY-SECOND AFFIRMATIVE DEFENSE

To the extent applicable, Plaintiff's claims for damages are barred, in whole or part, by Plaintiff's and Decedent's failure to mitigate damages.

TWENTY-THIRD AFFIRMATIVE DEFENSE

To the extent applicable, Defendants specifically assert the defenses of comparative negligence and comparative assumption of risk.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

To the extent applicable, Defendants' liability for non-economic damages is several rather than joint and should be prorated.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

To the extent applicable, Defendants are entitled to contribution from any person and/or entity whose negligence or other fault contributed to Decedent's alleged injuries and damages.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

To the extent applicable, if Plaintiff and/or Plaintiff's Decedent suffered or sustained the loss, damage, injury, harm, expense, diminution, or deprivation alleged, which Defendants deny, the same was caused in whole or in part or was contributed to by the negligence of Plaintiff's Decedent.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

The Complaint fails to state facts sufficient to sustain a claim for, or recovery of, punitive or exemplary damages.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by the First Amendment to the United States Constitution.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff's fraud and consumer protection claims are barred by reason of the Complaint's failure to allege the factual circumstances constituting that specific claim with particularity.

THIRTIETH AFFIRMATIVE DEFENSE

To the extent Plaintiff makes a claim for punitive damages or multiples of actual damages, Defendants assert that Plaintiff has not complied with federal or state statutory requirements to recover such damages.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Any claims for punitive and exemplary damages or multiples of actual damages, are barred by the Fourth, Fifth, Sixth, Eighth, and Fourteenth Amendments to the United States Constitution and the law of Pennsylvania and/or other applicable state law.

THIRTY-SECOND AFFIRMATIVE DEFENSE

While Defendants deny that they are liable for any punitive and/or exemplary damages (hereinafter "such damages") in this case, to the extent Plaintiff claims such damages, they cannot be sustained because any award of such damages, which are penal in nature, without according to Defendants the same protections that are accorded to criminal defendants, including the protection against unreasonable searches and seizures, self-incrimination, and the right to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate

Defendants' rights guaranteed by the Fourth, Fifth, Sixth, and Fourteenth Amendments to the United States Constitution and would also violate law of Pennsylvania and/or other applicable state law.

THIRTY-THIRD AFFIRMATIVE DEFENSE

With respect to Plaintiff's demand for punitive and exemplary damages, Defendants specifically incorporate by reference any and all standards or limitations regarding the determination and enforceability of punitive and exemplary damage awards which arose in the decisions of BMW of North America Inc. v. Gore, 517 U.S. 559 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, 532 U.S. 424 (2001), State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408 (2003), and Philip Morris USA v. Williams, 127 S. Ct. 1057 (2007).

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims should be dismissed and/or transferred due to improper and/or inconvenient venue or forum.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to <u>Buckman Co. v. Plaintiff's Legal Committee</u>, 531 U.S. 341 (2001).

THIRTY-SIXTH AFFIRMATIVE DEFENSE

To the extent applicable, Plaintiff's claims for damages are barred, in whole or part, by the doctrines of res judicata (claim preclusion) and/or collateral estoppel (issue preclusion).

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's breach of warranty claims are barred because Plaintiff failed to give Defendants timely notice of those claims.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Any and all actions taken by Defendants with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

THIRTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because Defendants have complied with all applicable regulations of the federal and state governments.

FORTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Defendants did not make any false statements to Plaintiff and/or Decedent.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff is not entitled to recovery against Defendants because the conduct alleged in the Complaint was not the proximate cause of any alleged loss suffered by the Plaintiff and/or Decedent.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff is barred from recovery because the representations and actions alleged by Plaintiff were not material, in that they were not likely to have affected the decisions or conduct of the Decedent, or to have caused the Decedent to have chosen differently, but for such alleged representations or actions, and in that the alleged representations and actions were not likely to have misled the Decedent acting reasonably under the circumstances.

FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff is precluded from recovery because the representations and actions alleged by Plaintiff were not intended to deceive the Decedent.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff and/or the Decedent has not sustained any injury or damages compensable at law.

FORTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff may not recover on the claims pleaded in the Complaint because the damages sought are too speculative and remote.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's consumer protection claims under the laws of the Commonwealth of Pennsylvania are barred because Pennsylvania's consumer protection act does not permit a Plaintiff to recover damages for personal injuries. Further, Defendants deny that Plaintiff has valid consumer protection claims under the laws of Pennsylvania, or any other State, Commonwealth or District whose laws are or later become relevant in the course of this multidistrict litigation. However, if such claims are found to exist, Defendants plead all available defenses under the Acts.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's allegations do not constitute a violation under the consumer fraud statutes of the Commonwealth of Pennsylvania.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

Defendants reserve the right to raise additional affirmative and other defenses as may be established by discovery and the evidence in this case. Defendants further reserve the right to amend their Answer and to add such counterclaims as may become necessary after reasonable opportunity for investigation and discovery.

DEMAND FOR TRIAL BY JURY

Defendants hereby demand trial by jury.

WHEREFORE, Defendants respectfully request that the Court:

- 1. Enter judgment in their favor on all claims alleged in the Complaint;
- 2. Award Defendants the costs, disbursements and reasonable attorneys' fees associated with these proceedings; and
- 3. Grant Defendants such other and further relief as the Court may deem just and proper.

Dated: New York, NY November 8, 2007

Respectfully submitted,

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